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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 490,609	01/25/2000	Roderick T. Bunch	SO-3170	7385

7590 05/21/2002

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/21/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/490,609

Applicant(s)

BUNCH ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This Office action is in response to the communication filed February 27, 2002, Paper No. 14.

Claims 25-28 and 31-35 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Rejection of claims 25-28 and 31-33 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's amendments and arguments filed February 27, 2002, Paper No. 14.

Rejection of claims 25-27 under 35 U.S.C. 102(e) as being anticipated by Hillman et al, Upton et al, Lee et al or Skoda et al is withdrawn in light of Applicant's amendments filed February 27, 2002, Paper No. 14.

Maintained Rejections

Claims 25-28 and 31-35 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed August 13, 2001, Paper No. 12.

Applicant's arguments filed February 27, 2002 have been fully considered but they are not persuasive. Applicants argue that a prima facie case for non-enablement has not been made by

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the examiner, and that the claims under consideration are not directed to identifying protein, nor to correlating protein level with carcinogenicity. Contrary to Applicants' assertions, the scope of the claims, drawn to methods of determining levels or patterns of carcinogenesis biomarkers in a cell, comprising the detection of nucleic acid molecules of SEQ ID Nos: 280, 317, 384, 465 and 488 by hybridization assays, is not enabled by the instant specification. The correlation between increased expression of the biomarker nucleic acids (of SEQ ID Nos: 280, 317, 384, 465 and 488) in rat hepatocytes following exposure to phenobarbital is not representative of the ability to determine levels or patterns of carcinogenesis in any cell. No evidence has been provided which teaches the correlation between any patterns of carcinogenesis in any and/or all cells and increased expression of the claimed biomarkers. The increased expression of known marker genes in hepatocytes following exposure to the known carcinogen phenobarbital is not correlative or representative of the ability to determine patterns of carcinogenesis in any cell using hybridization assays which detect the level of expression of the disclosed biomarkers comprising SEQ ID Nos: 280, 317, 384, 465 and 488.

Claims 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al, for the reasons of record set forth in the Office action mailed August 13, 2001, Paper No. 12.

Applicants have not provided any argument addressing the rejection of record.

Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Upton et al. for the reasons of record set forth in the Office action mailed August 13, 2001, Paper No. 12.

Applicants have not provided any argument addressing the rejection of record.

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Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al, for the reasons of record set forth in the Office action mailed August 13, 2001, Paper No. 12.

Applicants have not provided any argument addressing the rejection of record.

Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Skoda et al, for the reasons of record set forth in the Office action mailed August 13, 2001, Paper No. 12.

Applicants have not provided any argument addressing the rejection of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

May 19, 2002



SEAN McGARRY
PRIMARY EXAMINER